



Improvement in Physical Endurance by an Amino Acid Based hGH-Secretagogue: A Pilot Study

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ABSTRACT

Background: The ability of an optimized amino acid supplement (Protovale™) to increase serum growth hormone (hGH) levels after oral administration in both men and women has now been demonstrated, but evidence bridging repeated daily administration of the supplement to known benefits of hGH injections has not yet been established.

Methods: This pilot study included 12 [7 male, 5 female; age = 31±6 years; BMI= 25.7±3.8] healthy subjects. The supplement, a 2.9g/dose blend of l-lysine HCl, l-arginine HCl, oxo-proline, N-acetyl-l-cysteine, l-glutamine, and schizonepeta (aerial parts) powder, was taken on an empty stomach prior to bedtime every night for two weeks with no other lifestyle changes. Before and after the two-week period, a standard maximal aerobic fitness test of graded exercise using a metabolic cart was performed during morning hours in a post-absorptive state. Before and after study VO₂max values were compared with a paired t-test.

Results: After two weeks of supplementation, mean VO₂max increased by 6% from 44.9 ± 8.1 at baseline to 47.7 ± 9.2mL/kg/min (3.69 ± 0.96 to 3.91 ± 1.03L/min), demonstrating a statistically significant improvement from baseline (P=0.02).

Conclusion: Increased measures of endurance are a well-established outcome of synthetic recombinant human growth hormone (rhGH) injections in adults¹. Here we show that two weeks of daily supplementation with the amino-acid based hGH-secretagogue significantly increased VO₂max compared to baseline with no other lifestyle changes. A larger multi-center study is being planned.

INTRODUCTION

The low-dose amino acid based supplement Protovale™ has been shown to significantly raise endogenous hGH in healthy men and

women of a wide age range², and its mechanism of action has been correlated to its ability to suppress somatostatin³. The present pilot study investigated the benefits of continued daily use of the supplement over a two-week period on metabolic and endurance parameters. The study methodology was designed in accordance with a recent study that found positive metabolic outcomes with use of recombinant human growth hormone (rhGH) injections over a two-week period in healthy adult subjects.¹

METHODS

This clinical study comprised a cohort of 12 healthy subjects [7 males, 5 females; mean age = 31 ± 6 years; body mass index= 25.7 ± 3.8 ranging from 20.3 to 32.2 kg/m²]. Each subject reported to the Fitness Testing Facility (PEAK, University of Utah College of Health) after an overnight fast. Upon arrival, each subject underwent standard measurements of weight, height, body fat percent (Bod Pod), and resting metabolic rate (RMR, indirect calorimetry) by the university personnel. Daily calorie expenditure was estimated based on the additive evaluations of measured RMR, estimated Lifestyle and Activity (defined as the number of calories burned performing daily activities including working, playing, eating, etc.), and estimated exercise (defined as an estimate of the number of calories burned during exercise based on daily activity level).

Following the baseline measurements, subjects then consumed a standard breakfast (Egg McMuffin, 300 Calories; 12g fat; 29g carbohydrates; 18g protein). Subjects rested for a further 45 minutes to reach a post-absorptive state and then underwent a Maximal Aerobic Fitness Test of graded exercise, completed on a treadmill. Subjects' oxygen uptake was measured using a metabolic cart, and VO₂max quantified.

Subjects were then provided a two-week supply of the low-dose

amino acid based supplement Protovale™ (2.9g/dose blend of l-lysine HCl, l-arginine HCl, oxo-proline, N-acetyl-l-cysteine, l-glutamine, and schizonepeta (aerial parts) powder). Subjects were instructed to consume one dose of the supplement on an empty stomach, at least two hours after eating prior to bedtime, every night for the two-week study duration.

Following the final dose, each subject returned to the PEAK Fitness Testing Facility, University of Utah College of Health, after an overnight fast (without having consumed the last dose of the supplement since the previous night). Upon arrival each subject underwent the identical test protocols as the baseline test day. The data from the two measurement days were then analyzed. Statistical significance was set at p<0.05.

RESULTS

Results showed that mean VO₂max increased by 6% after the two-week period of supplementation with Protovale™ from 44.9 ± 8.1 at baseline to 47.7 ± 9.2mL/kg/min (3.69 ± 0.96 to 3.91 ± 1.03L/min) at two weeks, demonstrating a statistically significant differential effect compared to baseline (p=0.02). And while the present pilot study was not sufficiently powered to detect a significant change in mean RMR and estimated daily calorie expenditure, these parameters showed increased values over baseline following the treatment period.

Overall, we find that after two weeks of supplementation with Protovale™ (taken on an empty stomach, two hours after eating prior to bedtime, every night), endurance as measured by VO₂max in the post-absorptive state significantly improved with a measured 6% increase, p=0.02, and both RMR and estimated daily calorie expenditure numerically increased, however not sufficiently powered to achieve significance, evidencing the potential of the supplement to impart long-term fat burning effects.

DISCUSSION and CONCLUSIONS

The influence of growth hormone administration on metabolic parameters and overall energy expenditure has been documented.¹ Subsequent to the primary study showing that hGH is increased 8 fold, equivalent to 682%, after oral administration of Protovale™ p=0.01 vs.placebo², we sought to understand the ability of the amino acid based hGH secretagogue to impart consequential effects. Our study looked at the effects of daily consumption over a two-week period on metabolic and endurance parameters as consistent with a recent study using rhGH injections.¹

After two weeks of supplementation with Protovale™, we find that endurance as measured by VO₂max in the post-absorptive state significantly improved with a measured 6% increase over baseline, and that numeric increases in both RMR and estimated daily calorie expenditure were seen, despite this pilot study not being sufficiently powered to achieve significance in these measurements. Further research in this area may provide insight to potential effects on body composition and weight regulation by the amino acid based hGH secretagogue. A larger multi-center study is being planned.

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